510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN - 7 2012

APPLICANT INFORMATION

A.	Company Name:	KFx Medical, Corporation
B.	Company Address:	5845 Avenida Encinas Suite 128 Carlsbad, CA 92008
C.	Company Phone:	(760) 444-8844
D.	Company Facsimile:	(760) 602-9252
E.	Contact Person:	Gayle Hirota Director QA/RA

DEVICE IDENTIFICATION

A.	Trade Name:	KFx APPIANFx™ PEEK Suture Anchors and KFx APPIANFx™ PEEK Tissue Anchors
B.	Catalog Number:	KFX-MST-150 (5.0mm Suture Anchor) KFX-MST-160 (6.0mm Suture Anchor) KFX-GTO-160 (6.0mm Tissue Anchor)
C.	Common Name:	Bone Anchor
D.	Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
E.	Product Code:	MBI
F.	Device Panel:	Orthopedic
G.	Device Class:	Class II

IDENTIFICATION OF MODIFIED DEVICE

The KFx APPIANFx™ PEEK Suture Anchors and KFx APPIANFx™ PEEK Tissue Anchors are substantially equivalent to the KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle.

DEVICE DESCRIPTION

The KFx APPIANFx™ PEEK Suture Anchors consist of a fixation device comprised of a body with deployable legs, a wedge, and a disposable suture loop preloaded in a delivery (insertion) handle. The KFx APPIANFx™ PEEK Tissue Anchors consist of a fixation device comprised of a body with deployable legs and a cleated wedge preloaded in a

delivery (insertion) handle. Each device is intended for single use and may be used in arthroscopic and open procedures.

Devices are provided "STERILE"; sterilization is by radiation (E-Beam) and provides a sterility assurance level of 10^{-6}.

INTENDED USE

The intended use of the KFx APPIANFx™ PEEK Suture Anchors and KFx APPIANFx™ PEEK Tissue Anchors are for the fixation of soft tissue to bone in the shoulder, foot, ankle, knee, hand, wrist, and elbow.

BIOCOMPATIBILITY AND PERFORMANCE DATA

The materials used in the KFx APPIANFx™ PEEK Suture Anchors and KFx APPIANFx™ PEEK Tissue Anchors are biocompatible. The same materials are used in a myriad of legally marketed orthopedic devices.

Non-clinical test data (deployment, static pull-out, and cyclic suture retention testing) indicate that the device is safe and satisfies functional performance requirements when used as indicated and do not raise new issues of safety or effectiveness.

CONCLUSIONS DRAWN FROM STUDIES

The documentation provided demonstrates that the KFx APPIANFx™ PEEK Suture Anchors and KFx APPIANFx™ PEEK Tissue Anchors are substantially equivalent to the currently marketed predicate device and is safe and effective when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 7 2012

KFx Medical, Corporation
% Ms. Gayle Hirota
Director, Quality Assurance / Regulatory Affairs
5845 Avenida Encinas, Suite 128
Carlsbad, California 92008

Re: K120841
Trade/Device Name: KFx AppianFx PEEK Suture Anchors and KFx AppianFx PEEK Tissue Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: May 8, 2012
Received: May 9, 2012

Dear Ms. Hirota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1.6 Indications for Use

510(k) Number (if known): K120841

Device Name: KFx APPIANFx™ PEEK Suture Anchors and APPIANFx™ PEEK Tissue Anchors

Indications For Use: The KFx APPIANFx™ PEEK Suture Anchors and APPIANFx™ PEEK Tissue Anchors are intended for the fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow.

Specifically:

Shoulder: Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tenodesis, deltoid repairs

Foot and Ankle: Hallux valgus repairs, medial or lateral instability repairs/reconstructions, mid-foot reconstructions, metatarsal ligament repair

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, iliotibial band tenodesis, patellar tendon repair

Hand/Wrist/Elbow: Scapholunate ligament reconstructions, ulnar or radial collateral ligament reconstructions, tennis elbow repair, biceps tendon reattachment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120841

CONFIDENTIAL